

CLAIMS

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1. A biologically active composite solid shaped article comprising an outer layer and an inner core, wherein:

(a) the outer layer is an extrudable coating retaining the structural integrity of the inner core and consisting of :

- at least one polymeric component selected from the group consisting of hydrophobic cellulose polymers, acrylate (co)polymers, polyvinylpyrrolidone, polyethylene oxide, polyvinyl alcohol, poly(ethylene-co-vinyl acetate), and

- optionally at least one plasticizer for the said polymeric component,

(b) the inner core fills said outer layer and comprises:

- at least a biologically active ingredient, and

- an excipient for the said biologically active ingredient, said excipient comprising at least one hydrophilic cellulose polymer and an amphiphilic material, wherein the weight ratio of said hydrophilic cellulose polymer to said amphiphilic material is from 0.2 : 1 to 0.6 : 1.

2. A biologically active composite solid shaped article according to claim 1, wherein the hydrophilic cellulose polymer of the inner core is a hydroxyalkylalkylcellulose.

3. A biologically active composite solid shaped article according to claim 1 or claim 2, wherein the hydrophilic cellulose polymer of the inner core is hydroxypropylmethylcellulose.

4. A biologically active composite solid shaped article according to any of claims 1 to 3, wherein the amphiphilic material of the inner core has both a portion derived from a glyceride and a portion derived from a polyethylene glycol ester.

5. A biologically active composite solid shaped article according to any of claims 1 to 4, wherein the weight ratio of the hydrophilic cellulose polymer to the amphiphilic material in the blend of the inner core is from 0.3 : 1 to 0.6 : 1.

6. A biologically active composite solid shaped article according to any of claims 1 to 5, wherein the content of the biologically active ingredient in the inner core is in a range from 0.1 to 50% by weight.
- 5 7. A biologically active composite solid shaped article according to any of claims 1 to 6, wherein the content of the hydrophilic cellulose polymer in the inner core is in a range from 10 to 40% by weight.
8. A biologically active composite solid shaped article according to any of
10 claims 1 to 7, wherein the content of the amphiphilic material in the inner core is in a range from 30 to 85% by weight.
9. A biologically active composite solid shaped article according to any of claims 1 to 8, wherein the polymeric component of the outer layer is selected
15 from the group consisting of hydrophobic cellulose polymers, acrylate (co)polymers, polyvinylpyrrolidone, polyethylene oxide, polyvinyl alcohol, poly(ethylene-co-vinyl acetate) and mixtures thereof.
10. A biologically active composite solid shaped article according to any of
20 claims 1 to 8, wherein the plasticizer for the polymeric component of the outer layer is selected from the group consisting of glycerol, polyols, esters formed between glycerol and acetic acid, sugars, glycol glycoside, poly(ethylene glycol), fatty acids and esters thereof with polyethylene glycol, propylene glycol, butylene glycol, phthalate esters, sebacate esters, and mixtures thereof.
- 25 11. A biologically active composite solid shaped article according to any of claims 1 to 10, wherein the outer layer and/or the inner core further comprise one or more further excipients selected from the group consisting of emulsifiers, surface-active agents, thickening agents, gelling agents, organic
30 and inorganic pigments, UV-absorbers, stabilisers, odor masking agents, viscosity enhancers, antioxidants, preservatives, sequestering agents, flavoring agents, buffers, extenders and densification agents.

12. A biologically active composite solid shaped article according to any of claims 1 to 11, wherein the biologically active ingredient is selected from the group consisting of therapeutic agents, diagnostic agents, cosmetic agents, prophylactic agents, insecticides, pesticides, herbicides, plant growth
5 regulators, fertilisers, crop treatment agents, anti-microbial agents, fungicides and bactericides.

13. Use of a hydrophilic cellulose polymer in combination with an amphiphilic material, wherein the weight ratio of the said hydrophilic cellulose polymer to
10 the amphiphilic material in the said combination is from 0.2:1 to 0.6:1, for manufacturing at least a portion of a biologically active formulation.

14. Use according to claim 13, wherein the biologically active formulation is a biologically active composite solid shaped article.

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15. Use according to claim 14, wherein the biologically active composite solid shaped article comprises an inner core made from the said combination.

16. Use according to any of claims 13 to 15, wherein the said portion of the
20 biologically active formulation additionally includes from 0.1 to 50% by weight of a biologically active ingredient.

17. A process for making the core material of a biologically active formulation, comprising extruding a blend of at least a biologically active ingredient, at
25 least a hydrophilic cellulose polymer and at least an amphiphilic material, the weight ratio of the hydrophilic cellulose polymer to the amphiphilic material in the said blend being from 0.2:1 to 0.6:1, at a temperature within the range from 20°C to 60°C.

30 18. A process for making of a biologically active formulation comprising an inner core and an outer layer, the said process comprising:

- extruding a blend of at least a biologically active ingredient, at least a hydrophilic cellulose polymer and at least an amphiphilic material, the

weight ratio of the hydrophilic cellulose polymer to the amphiphilic material in the said blend being from 0.2:1 to 0.6:1, at a temperature within the range from 20°C to 60°C, and

- co-extruding the said blend with the components of the outer layer.

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